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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,710	03/30/2000	Anders Dahlqvist	3377/99-Util	9098

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/537,710	DAHLQVIST ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

2. Applicant's response to the Office Action mailed December 1, 2005 on September 8, 2006 is acknowledged.

Claim Disposition

3. Claims 30-32 are pending and are under examination.

Withdrawn-Specification Objection

4. Previous objections to the specification are withdrawn by virtue of submission of an amendment.

Drawing

5. The Drawing filed on March 1, 2006 has been accepted by the examiner.

Sequence Compliance

6. The instant application is in compliance with the sequence rules.

Maintained and New - Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 30-32 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 30-32 are drawn to methods of using transgenic cells or transgenic organism having a nucleotide sequence that encodes an enzyme that is claimed solely by function and without any structural limitations. The claims are directed to a genus of nucleotides that are not adequately described as a skilled artisan cannot envision the detailed chemical structure of the fragments encompassed in the claims. The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials'. University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel,

25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. In the instant specification, a novel enzyme activity is described as a phospholipids: diacylglycerol transferase (PDAT). Some plants, and not others, have this activity (see page 16 of the instant specification). A yeast gene, YNR008w, was tested for this activity and was confirmed to be a PDAT that can be over expressed in yeast and *A. thaliana* to increase fatty acid content in cells. The specification also describes numerous shorter DNA's and encoded proteins putatively described as PDAT genes; however, no testing on these gene fragments has been preformed to confirm the proposed function. Thus, one species of the claimed genus has been fully described, that is the use of the S. cerevisiae sequence (SEQ ID NOs:1 and 2) to produce transgenic organism with increased triacylglycerol production. The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and

structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Further, no relationship between the disclosed species and the structures of the other proposed species is described. No common characteristics, other than the enzyme function, is required in the claims. Thus, one of skill in the art would be unable to predict the structure of other members of this genus based on the instant disclosure. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

8. Claims 30-32 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of making triacylglycerol using a host organism transformed with a gene encoding PDAT from *S. cerevisiae* (SEQ ID NO:1), does not reasonably provide enablement for methods using any gene encoding any PDAT from any source absent any structural limitations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in

the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988)*. The factors most relevant to the instant invention are discussed below. To find additional PDAT genes and use them in the claimed methods would require undue experimentation.

In the instant specification, a novel enzyme activity is described as phospholipids: diacylglycerol transferase (PDAT). Some plants, and not others, have this activity (see page 16 of the instant specification). A yeast gene, YNR008w, was tested for this activity and was confirmed to be a PDAT that can be over expressed in yeast and *A. thaliana* to increase fatty acid content in cells. The specification also describes numerous shorter DNA's and encoded proteins putatively described as PDAT genes; however, no testing on these gene fragments has been performed to confirm this function.

The instant specification proposes 5 additional species of PDAT genes (6 total) and provides guidance and working examples to test for their activity. However, the nature of the invention is that genes encoding PDAT must be known to practice the claimed invention; the prior art provides none of these with respect to structure and related function. Due to the lack of a structure/function correlation analysis of the yeast PDAT gene, proven to function as a PDAT in the instant specification, it is wholly unpredictable which of the disclosed fragments of yeast and plant sequences encode additional PDATs. Moreover, the full-length sequences are not disclosed; only ESTs are disclosed. While a skilled artisan could find additional full length sequences using the disclosed ESTs and functional assays, the ability to find does not fulfill the statutory requirement of the ability to make. Having the instant disclosure in full view of the

prior art, one of skill in the art would be unable to predict the structure of PDAT genes so as to be able to make them, even in the likeness of SEQ ID No:1 (the *S. cerevisiae* sequence).

Additionally, the claims are not enabled for methods to produce triacylglycerol with uncommon fatty acids in organisms without the ability to natively produce triacylglycerol with uncommon fatty acids. To make some cells that produce TAG with uncommon fatty acids would require undue experimentation absent adequate guidance. Page 1 of the instant specification describes the claimed invention as being able to produce uncommon fatty acids "in combination with a gene for the synthesis of an uncommon fatty acid"; the PDAT gene does not regulate this process. Thus, to effectively practice the claimed methods, one would be required to use organisms that naturally produce uncommon fatty acids or to use organisms also transformed with a gene for the synthesis of an uncommon fatty acid. The specification provides no guidance or working examples for producing uncommon fatty acids in the absence of uncommon fatty acid genes (either endogenous or exogenous).

Moreover, the claims are directed to a method to produce host cells with increased overall oil content and the instant specification is not enabled for said method. The specification describes methods that increase the fatty acid content of host cells wherein a PDAT gene is over-expressed (see page 19, and Table 2), however, the specification does not describe increasing the overall oil content of the host organism, which is a distinct method. As noted in WO 96/38573 on page 1, "[c]urrently, there are no documented demonstrations of increase in oil content by transgenic means...[i]n contrast, increased in the proportions of some strategic fatty acids have been achieved by the introduction of various plant fatty acid biosynthesis and

acyltransferase genes in oilseeds". The state of the art provides no examples to support the scope of the claimed invention.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art. Further, attempting to find additional PDAT genes and use them in the claimed methods or to make some cells that produce TAG with uncommon fatty acids or a construct a method to produce host cells with increased overall oil content would constitute undue experimentation absent adequate guidance in the specification. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 30-32 remain rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 30 remains indefinite for equating "a nucleotide sequence" with "a DNA encoding" as this lacks parallel construction; both should recite either nucleotide or DNA for clarity, one term not both (see also claims 31 and 32 where the same language appears). The

claim is also unclear following the "whereby" clause because it is unclear if the phrases that follow are meant to further limit the nucleotide sequence contained in the transgenic cell or organism? If so, the claim should read, "whereby said nucleotide sequence". In addition, does the phrase beginning "in which" mean to define a function of the nucleotide sequence (or DNA)? Further, the phrase "in which the said enzyme" represents improper English, it is suggested that "the" is deleted from the phrase.

Response to Applicant's Arguments:

10. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments presented on pages 5-7 pertaining to the 112 first paragraph rejections have been considered in full, however, are not persuasive. With regard to the issue raised of the claims encompassing a genus of proteins, the claims read on fragments and variants of the claimed sequences based on the language "a nucleotide encoding SEQ ID NO:2", as this is read as "any nucleotide or portion thereof". With regard to the 112, second paragraph rejection, the claims still recite "nucleotide" and "DNA" together. It is suggested that the claim is amended and only nucleotide is recited in the claims, for example, "said nucleotide". Thus, the rejection remains.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

11. Previous rejection of the claims under 35 U.S.C. § 102 is withdrawn by virtue of applicant's arguments.

Conclusion

12. No claims are presently allowable.

13. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner 11/20/06

HOPE ROBINSON
PRIMARY EXAMINER